Remarks

Claims 1, 21, 30, 33, and 36-43 are under consideration.

Claims 2-20, 22-29, 31, 32, 34, and 35 have been canceled without prejudice to advance prosecution of this application.

New claim 39 is specifically directed to the currently elected species.

New claims 40 and 41 are directed to pharmaceutical compositions comprising the polypeptides of claims 38 and 39, respectively. Support for these claims can be found in the specification at page 9, lines 21-24, and in original claim 10.

New claims 42 and 43 are directed to isolated nucleic acids encoding the polypeptides of claims 38 and 39, respectively. Support for these claims can be found in the specification at page 9, lines 19-20, and in original claim 18.

Claims 1 and 21 have been amended to incorporate the listing of amino acid residue substitutions found in now canceled claims 22, 23, and 24. Claim 21 was also amended to delete reference to the epitope regions, which no longer need to be mentioned in the claim, since all of the substitutions are now specified.

Claim 38 has been amended to conform with the amendment made to claim 21, i.e., to delete reference to epitope region (c).

All of the newly added claims read on the elected species. No new matter is added by these amendments.

Enablement Rejections.

Claims 1, 21, 30, 33, and 36-38 stand rejected as allegedly failing to comply with the enablement requirement of the first paragraph of 35 U.S.C. §112. This rejection is traversed.

Currently amended claims 1 and 21 and the claims that depend therefrom are directed to a finite genus of specific polypeptides, which comprise SEQ ID NO: 1 with at least one specified amino acid residue substitution. The application provides guidance on how to determine to immunological properties of the polypeptides and discloses the biological activity associated with human erythropoietin (EPO). Furthermore, the biological activity and amino acid residue sequence of EPO were well known in the art at the time the application was filed, as indicated by the references listed in the background section of the invention (see

e.g., page 2). Methods for assessing the level of immunogenicity of the polypeptides were also known before the filing date of the application (see *e.g.*, pages 3-4 of the specification).

In addressing enablement, the Federal Circuit has held that a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides adequate guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). In the present case, the amount of experimentation meets both alternative criteria from *In re Wands*. First, the required experimentation is routine in nature. Second, the application provides precise guidance with respect to the direction of experimentation, since the amino acid residue sequences of the polypeptides are set forth in the claims, including all of the possible amino acid residue substitutions, and the methods for gauging immunogenicity are described in the specification and were known in the art. This is even more evident in the case of claims 36 and 37, which specify the measure of immunogenicity, and for claims 38-43, which are narrowly drawn to the elected species. In fact, claim 38 is directed to a genus of only three polypeptides, each with a single amino acid residue substitution in SEQ ID NO. 1, while claim 39 is directed to a genus of only seven polypeptides - three having a single substitution, one having three substitutions, and three having two substitutions in SEQ ID NO: 1. Clearly, any experimentation needed to practice clams 38 and 39 or their dependent claims 40-43 would be neither excessive nor undue.

Withdrawal of this rejection is warranted.

Reconsideration and early passage of the application to issued is solicited.

Respectfully submitted,

Dated: 18 December 2007

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